



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Roger P. Jackson

Serial No.: 10/767,646

Date: March 29, 2010

Filed: January 29, 2004

Group Art Unit: 3773

Docket No.: 10,390

Exam: Julian W. Woo

For: CLOSURE FOR OPEN HEADED MEDICAL IMPLANT

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Kansas City, Missouri

Appeal No. _____

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

ATTENTION: Board of Patent Appeals and Interferences

APPELLANT'S BRIEF

This brief is filed under 37 CFR 41.37 and in support of the Notice of Appeal in this application on January 27, 2010.

The fees required under 41.2(b)(2) were previously submitted with the Appellant's Brief dated April 13, 2009 as a large entity in the amount of \$540.

Consequently, no additional fees are believed due. If

additional fees are found to be due, please charge them to deposit account No. 50-1253.

I REAL PARTY IN INTEREST

The applicant Roger P. Jackson is the real party in interest.

II RELATED APPEALS AND INTERFERENCES

The following is a related patent application on appeal to the Board of Appeals:

Serial No. 10/142,614 which appeal has only recently been filed and with respect to which no Examiner's response has been received and to which no decision by the Board of Appeals has been entered.

III STATUS OF CLAIMS

Claims rejected: 1-3 and 5-14

Claims allowed: None

Claims withdrawn: None

Claims objected to: None

Claims cancelled: 4 and 15

Claims appeals: 1-3 and 5-14

IV STATUS OF AMENDMENTS

There are no outstanding or pending amendments.

V SUMMARY OF CLAIMED SUBJECT MATTER

The following are summaries of the independent claims indicating where the cited structure appears in the specification and drawings.

Claim 1 A closure plug {6, page 9, line 11 to page 14, line 22 and see Figs. 1 to 8} adapted for use with an open-headed medical implant {5, page 9, line 11 to page 14, line 22} having a pair of spaced and interiorly threaded arms {21 and 22, page 9, line 21 to page 10, line 23}; said plug comprising:

- a) a body {35, page 10, line 11 to page 10, line 19} sized and shaped to be threadedly received between and in the spaced arms of the implant head {13, page 9, line 16 to page 10, line 1}; said body having a radially outward surface {40, page 10, lines 13-23} that has a thread {41, page 10, lines 19-23} thereon that is sized and shaped to threadedly mate with the threaded arms of the implant;
- b) said body having a top surface and a bottom surface {49 and 50, page 11, lines 4-7}; said top surface of said

body having at least one bore {44, 45 and 46, page 11, lines 1-5} therein sized and shaped to receive a removal tool {78, page 13, line 17 to page 14, line 9} and extending generally axially entirely through said body from top to bottom thereof and opening onto said top surface {page 11, lines 5-7 and Fig. 8}; wherein:

- c) said bore is spaced from and positioned between both a central axis {A, page 10, lines 15-16} of said body and a periphery {48, page 11, line 4} of said body {page 11, lines 1-11}; and
- d) a break-off head {36, page 10, line 11 to page 13, line 9} attached to said body at a neck {54, page 11, lines 12 to 20} and being breakable from said body at a preselected torque {page 12, line 23 to page 13, line 4}; said neck being axially aligned with said body {page 11, lines 1 to 20 and Figs. 1 to 3}; said break-off head being positioned so as to be axially located above said body and at least a portion of said bore {page 11, line 12 to page 13 line 9, and especially Fig. 5}; said break-off head being free of pass through openings so as to block axial access by the removal tool to said bore until said break-off head breaks from said body {page 3, line 21 to page 4, line 7; page 10,

line 11 to page 14, line 22 and especially as seen in Fig. 5}.

Claim 14 In a plug closure {6, page 9, line 11 to page 14, line 22 and see Figs. 1 to 8} for operably closing a top of a channel {23, page 9, line 21 to page 10, line 2} between two arms {21 and 22, page 9, line 21 to page 10, line 23} of an open headed medical implant {1, page 9, lines 8-15, and Fig. 1}, the improvement comprising:

- a) said closure having at least a pair of bores {44, 45 and 46, page 9, line 23 to page 11, line 1, page 14, line 22, and Fig. 8} each being positioned in spaced relationship to both an axis of said closure and to a periphery of said closure; said bores being parallel to said axis and being accessible from a top of said closure {page 11, line 1 to page 14, line 9}; and
- b) a break-off head {36, page 10, line 11 to page 12, line 6} attached to the top {49, page 11, lines 12-15} of said closure and operably blocking axial access to said bores such that a removal tool {78, page 13, line 16 to page 14, line 22, and see Fig. 8} cannot be axially inserted into said bores when said break off head is attached to said closure; said break off head being

breakable from the closure upon application of a preselected torque {page 12, line 23 to page 13, line 4} to said break-off head, when said closure is positioned between the arms, said break off head being free of openings providing axial access to at least a portion of each of said bores such that said bores are positioned so as to be axially inaccessible by the removal tool until said break-off head is broken from said closure {page 3, line 21 to page 4, line 7; page 10, line 11 to page 14, line 19; and especially as seen in Fig. 5}.

VI GROUND OF REJECTION TO BE REVIEWED

- 1) Is claim 14 properly rejected under 35 U.S.C. §102(b) as being anticipated by Dent (GB2140523A)?
- 2) Are Claims 1 to 3, 5, 6 and 13 properly rejected under 35 U.S.C. §103(a) as being unpatentable over Sherman et al. (5,797,911) in view of Dent (GB2140523) and further in view of Johnson (1,300,275)?
- 3) Is Claim 9 properly rejected under 35 U.S.C. §103(a) as being unpatentable over Sherman in view of Dent and Johnson and further in view of Wagner (5,334,203)?
- 4) Is Claim 10 properly rejected under 35 U.S.C. §103(a)

as being unpatentable over Sherman in view of Dent and Johnson and further in view of Parker, et al.

(6,053,078)?

- 5) Are Claims 7, 8, 11 and 12 properly rejected under 35 U.S.C. §103(a) as being unpatentable over Sherman in view of Dent and Johnson and further in view of Reed (6,261,039)?

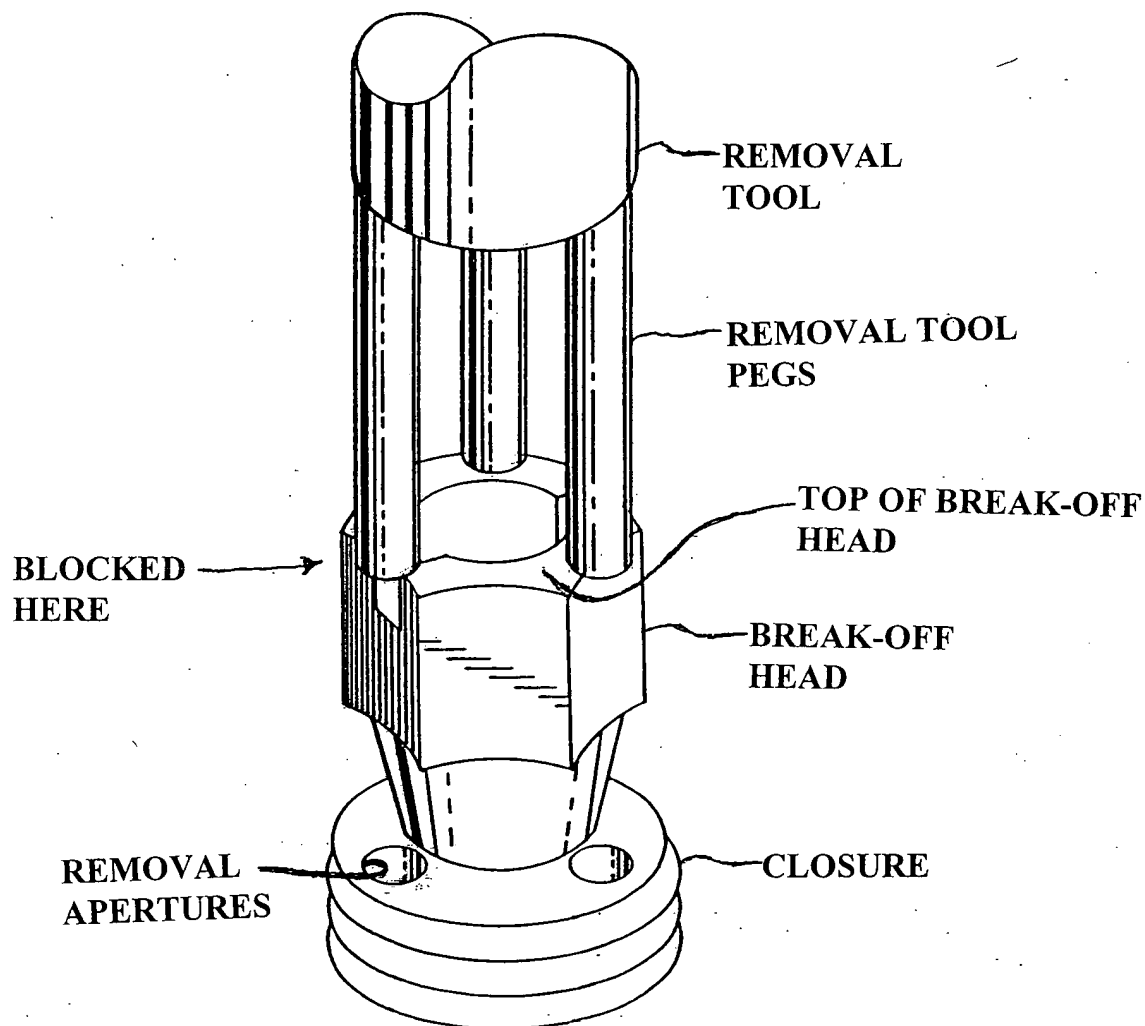
VII ARGUMENTS

Open headed bone screw and hook implants have potentially splayable arms that receive a rod in a channel located between the arms in a channel generally defined by the arms. Thereafter, a closure is secured between the arms and over the rod to frictionally hold the rod in place relative to the screw or hook. If too much torque is applied to the closure the arms may bend or splay outward, thereby releasing the closure and allowing the implant to catastrophically fail. Break-off heads are provided to limit the torque to a range that will not splay the arms. That is, when a certain torque is reached the head breaks away with the intent of preventing overtorquing and this normally prevents splaying of the arms.

Applicant is a spinal surgeon and has recognized that it is possible to circumvent the break-off head torque limiting

structure, as provided for in the prior art. In particular, where structure, such as apertures in the body of the closure, is provided for removal of the closure, it is possible for the removal tool to be inadvertently or deliberately used to insert the closure. If this occurs and the removal tool can simultaneously engage the break-off head and the removal structure, then the closure can be overtorqued without the torque limiting function of the break-off head breaking away. Such a problem is seen in the cited prior art of Dent where there are pass through apertures drilled through the break-off head and into the body (see especially apertures 20 in Figs. 9 and 14 of Dent). Because there is a direct and unobstructed path for the removal tool to follow down the apertures 20, the tool can engage both the break-off head and the apertures in the closure body simultaneously, possibly leading to the closure being overtorqued and causing it to fail. Applicant resolves this problem by drilling the removal apertures (44, 45 and 46, see Fig. 5 of Jackson) from the bottom of the closure, such that the break-off head 36 overlaps and obstructs at least a portion of each aperture and prevents a surgeon from inserting a removal tool into the removal apertures until the break-off head is removed.

The following is an illustration showing how applicant's closure blocks a removal tool.



1) Rejection of Claim 14 based on anticipation by Dent

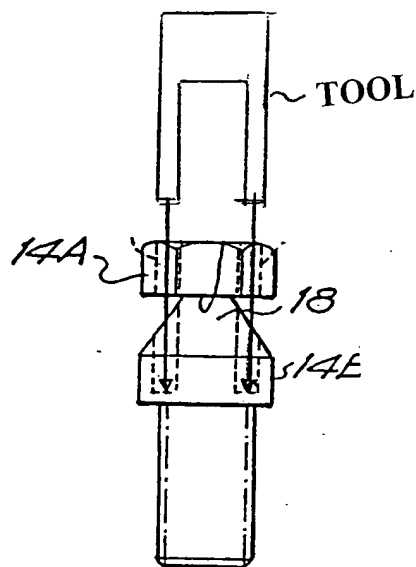
The device shown in the Dent reference is non analogous prior art. It is not for use with a medical implant, but rather various mechanical devices such as electrical connectors.

Further, the Dent device is not used to resolve the same problem as applicant's invention wherein a closure is designed to prevent splaying of the upstanding arms of a medical implant receiver. Therefore, it is urged that Dent fails to meet either test for analogous art in that it is neither directed to the same field of art, nor does it teach, show or suggest how to resolve the same problem.

While it is urged that the Dent reference is improperly cited, as it is non analogous prior art, the Dent reference further does not show applicant's invention and actually teaches a structure that is contrary to applicant's invention.

In particular, Claim 14 calls for a closure having a break-off head and at least a pair of bores in the closure that are accessible from the top, but which are operably blocked from access by the break-off head when the head is in place.

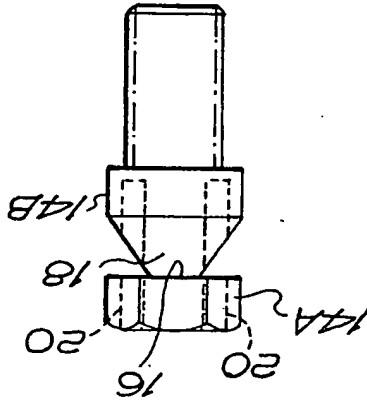
Shown below is Fig. 14 of the Dent reference with an added tool to illustrate that a tool can simultaneously pass through both bores in the break-off head and the closure body before the break-off head is broken away.



Dent
Fig. 14

The last Office action states that Dent discloses a "closure (14A) having at least a pair of bores (20) each positioned in spaced relationship to both an axis of the closure and to the periphery of the closure"---"the break-off head [14B] being free of bores providing axial access to the bores by a removal tool". As noted before, the bores in the break-off head of Dent allow free access to the bores in the body before the head is broken away. The construct proposed by the Office action is argued to be found when the device shown in Fig. 14 is turned upside down and the identification of elements 14A and 14B is reversed.

Shown below is Fig. 14 of Dent turned upside down.



Dent
Fig. 14
upside down

When Dent Fig. 14 is turned upside down, the function of the elements does not change. In particular, the break-off head 14A remains the break-off head and the body 14B remains the body, whether right side up or upside down. With respect to Dent and

as before noted, Dent is not directed to a closure that is received between a pair of arms separated by a channel, but rather to a bolt or screw received in a fully surrounding bore. As such, the Dent device has no arms that are likely to splay under too much torque. As can be seen from the drawings, the Dent device has sets of apertures that pass through both the break-off head and part of the body and both sets are axially aligned with one another. Consequently, a tool with pegs that can penetrate the break-off head apertures can also inadvertently or deliberately be pushed at the same time into the apertures in the closure body. This can lead to overtorquing of a closure and in applicant's device consequent splaying of the arms in direct contradiction to applicants's claim language and intent of the invention, as called for in Claim 14.

In the Office action on page 3, fourth line up from the bottom, it is indicated that the preamble of Claim 14 is merely a statement of intended use and does not pose any structural limitations on the claims to render them patentably distinct over Dent. Applicant strongly disagrees with this position, for the following reason. Claim 14 recites "...when said closure is positioned between the arms." In order for this phrase to make any sense, one must refer to the preamble, which recites "...a channel between two arms of an open headed medical implant." Since one skilled in the art would be familiar with the usual sizes and shapes of open headed medical implants, such a person would use this knowledge to infer the size of the Claim 14 device. Therefore, the preamble of Claim 14 is "'necessary to give life, meaning, and vitality' to the claim, ...[and] should be construed as if in the balance of the claim." Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999), see MPEP 2111.02.

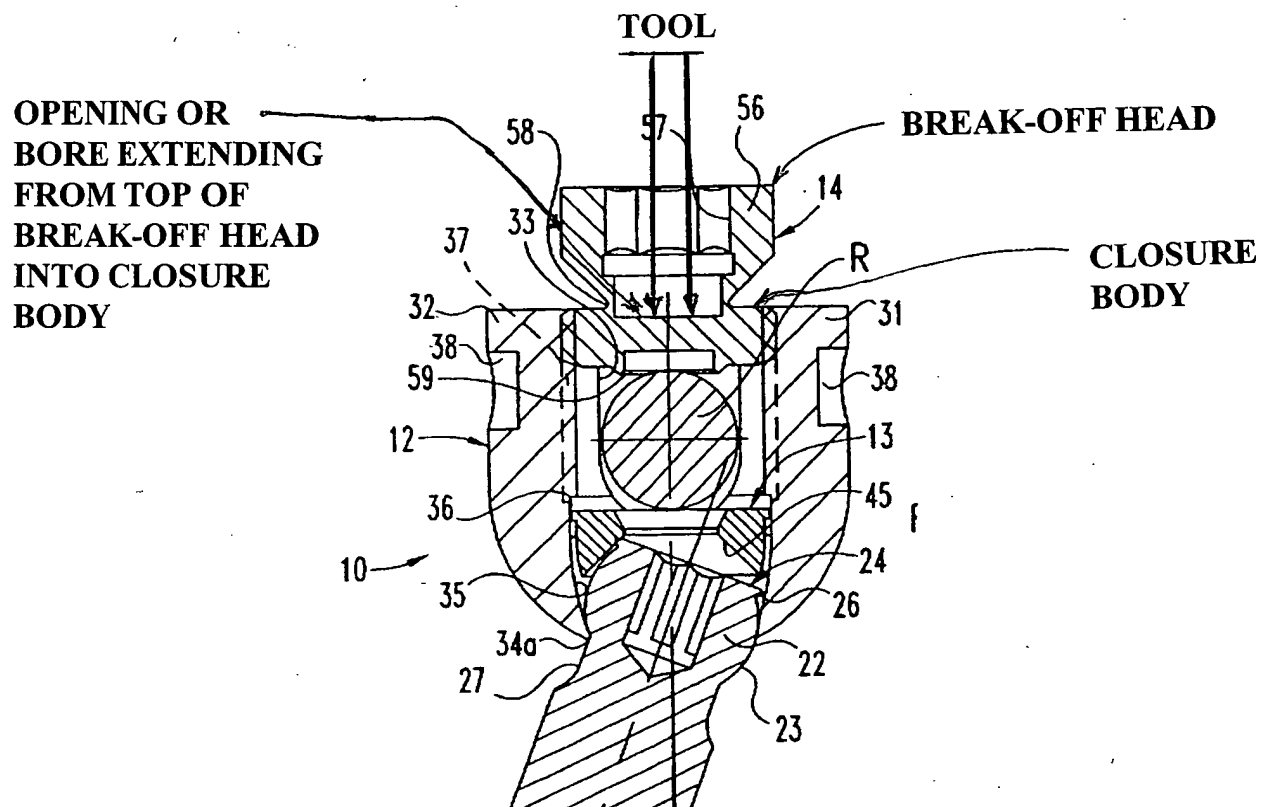
Dent fails to show, suggest or teach the elements called for in Claim 14 and, consequently, it is urged that Claim 14 is not anticipated by Dent, even if Dent were analogous art which it is not. Therefore, reversal of this rejection is requested.

2) Rejection of Claims 1 to 3, 5, 6 and 13 as obvious over Sherman in view of Dent and further in view of Johnson

It is noted that Johnson is also directed to non analogous prior art. Johnson is not directed to an implant for medical use. More importantly, the problem to be resolved by applicant (to prevent splaying of the receiver arms caused by overtorquing of the closure) is not found in Johnson and Johnson neither shows or suggests how to overcome the problem.

Furthermore, even if Johnson were analogous prior art, independent Claim 1 calls for a closure plug having a top surface with at least one bore to receive a removal tool and a break-off head wherein the break-off head is positioned to block access to any removal bore in the body until the break-off head is broken away. Johnson makes no such teaching.

The following is Fig. 2 of Sherman, et al. shown in conjunction with a proposed tool with a path available to a tool shown by lines added to show insertion into and through the break-off head.



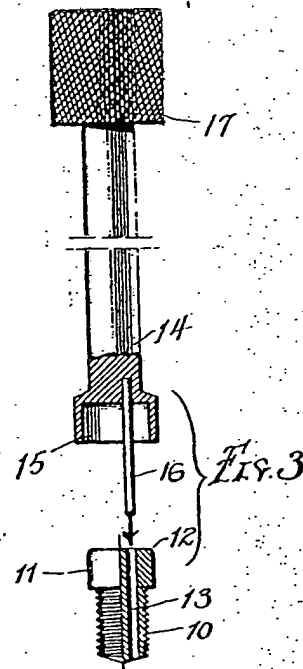
Sherman et al

Fig. 2

Sherman, et al. clearly show that the device shown in that patent has a central bore in the break-off head that extends into the body of the closure that is shown and which allows axial access, before the break-off head is broken away, to the remainder of the bore that is located in the body. The above figure shows how a tool can penetrate both the break-off head and the body at the same time. There is no other bore or aperture on the upper side of the Sherman, et al. device after the head breaks away than the part of the bore that is accessible at all times down the center of the break-off head. Consequently, Sherman, et al. fails to prevent access to the bore in the body when the head is attached contrary to applicant's invention.

Fig. 3 of Johnson is shown below.

Johnson



Johnson is also not directed to a bone screw closure, but rather, a bolt that goes into a surrounding bore and a removal tool. The bolt has a non-axial aperture in the top thereof. Johnson has no break off head, as can be clearly seen in Figs. 1 to 5. The aperture in the top of the bolt is designed to be used for both insertion and removal and the aperture is always accessible by the tool, again in contradiction to applicant's invention.

Consequently, it is urged that in each of Sherman, et al., Dent and Johnson, the bore (apertures or openings) on the top of the closure body (the bolt or the other structure) which remains after a break-off head breaks away (where such occurs) is always available for access by a tool and in none of the devices does a break-off head block access to the removal apertures or bores until the break-off head is removed. Consequently, it is urged that the cited references, whether taken singly or in combination fail to teach or suggest the claimed invention and that these claims are non-obvious to one having ordinary skill in the art. Therefore, it is urged that these claims are patentable under the standards set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ. 459 (1996).

While only Claim 1 was discussed specifically, all of the remaining claims of this rejection are urged to distinguish over the cited art for the same reasons as discussed for Claim 1.

3) Rejection of Claim 9 as obvious in view of a combination of Sherman in view of Dent and Johnson and further in view of Wagner

Claim 9 is dependent from Claim 1 and is urged to distinguish over all of the references, except Wagner for the same reasons as were discussed previously with respect to Claim 1 in Section 2. Wagner is cited for showing that the bores are spaced 120° apart. Thus, Wagner does not add anything to the other references with respect to showing elements of Claim 9 that are missing in the other cited references and also fails to show how such apertures would function with a break-off head or how to add a break-off head to cooperate with them to block the apertures until the head breaks away. Consequently, it is urged that Claim 9 is also not made obvious by the art of the present rejection.

4) Rejection of Claim 10 as obvious in view of combination of Sherman, Dent, Johnson and Parker

Claim 10 depends from Claim 1 and is urged to overcome the cited references except for Parker for the same reasons as discussed for Claim 1 in Section 2. Parker is cited as showing four bores. Parker is urged to not show any of the elements that are missing from the other references that were discussed with respect to Claim 1. Consequently, it is urged that Claim 10 is not obvious to one having ordinary skill in the art in view of the cited references of this rejection.

5) Rejection of Claims 7, 8, 11 and 12 as obvious in view of
a combination of Sherman, Dent, Johnson and Reed

Claims 7, 8, 11 and 12 depend from Claim 1 and are urged to distinguish from the cited references, except for Reed for the same reasons as were discussed for Claim 1 in Section 2. Reed is cited as showing an axially extending bore from the bottom to a top of a structure. It is noted that Reed is not directed to a closure that goes between spaced arms. The Reed device receives a bolt in an aperture that is always accessible. Consequently, it is urged that Reed does not provide, nor in any way suggest the elements missing from the other references that are called for in this group of claims. Therefore, it is urged that Claims 7, 8, 11 and 12 are also not obvious in view of the art of record of this rejection.

In summary, it is urged that the cited references fail to anticipate, teach or suggest applicant's claimed inventions and that none of the pending claims are anticipated by the cited prior art or obvious to one having ordinary skill in the art in view of the references of record.

VIII CLAIMS APPENDIX

Claim 1 A closure plug adapted for use with an open-headed medical implant having a pair of spaced and interiorly threaded arms; said plug comprising:

- a) a body sized and shaped to be threadedly received between and in the spaced arms of the implant head; said body having a radially outward surface that has a thread thereon that is sized and shaped to threadedly mate with the threaded arms of the implant;
- b) said body having a top surface and a bottom surface; said top surface of said body having at least one bore therein sized and shaped to receive a removal tool and extending generally axially entirely through said body from top to bottom thereof and opening onto said top surface; wherein:
- c) said bore is spaced from and positioned between both a central axis of said body and a periphery of said body; and
- d) a break-off head attached to said body at a neck and being breakable from said body at a preselected torque; said neck being axially aligned with said body; said break-off head being positioned so as to be axially located above said body and at least a

portion of said bore; said break-off head being free of pass through openings so as to block axial access by the removal tool to said bore until said break-off head breaks from said body.

Claim 2 The closure plug according to Claim 1 wherein:

- a) there are a pair of spaced bores extending into said body from the top surface thereof.

Claim 3 The closure plug according to Claim 1 wherein:

- a) said body is generally cylindrical in shape.

Claim 4 (Canceled)

Claim 5 The closure plug according to claim 1 wherein:

- a) said body includes at least a pair of said bores in the top thereof; and
- b) said neck is positioned between said bores.

Claim 6 The closure plug according to Claim 1 wherein:

- a) said break-off head has a tool grippable outer surface for operably rotating said closure during insertion into an implant and said neck being sized and shaped such that said break-off head breaks

from said body when a preselected torque is applied to said break-off head by such a gripping tool with a generally clean profile at said top surface.

Claim 7 The closure plug according to Claim 1 wherein:

- a) said closure includes an axial threaded bore passing entirely through said body from a top to a bottom thereof.

Claim 8 The closure plug according to Claim 7 in combination with:

- a) a threaded set screw sized and shaped to be received in said axial bore; said axial set screw being also sized and shaped to extend outward from said body bottom surface when said screw is fully installed therein.

Claim 9 The closure plug according to Claim 1 wherein:

- a) said body top surface has three spaced tool receiving bores located therein; each of said bores being located at a common radius from said body central axis and being spaced at 120° from adjacent tool receiving bores.

Claim 10 The closure plug according to Claim 1 wherein:

- a) said body top has four spaced tool receiving bores each being located at a common radius from said body central axis and being evenly spaced from adjacent tool receiving bores.

Claim 11 The closure plug according to Claim 1 wherein:

- a) said body includes an axial extending bore from the bottom to near the top thereof; said axial bore being located beneath said neck and being accessible from a top of said body when said break-off head breaks away from said body.

Claim 12 The closure plug according to Claim 11 wherein:

- a) said axial bore is threaded.

Claim 13 The closure plug according to Claim 1 including:

- a) a tool having a grippable handle and an engagement face; said face including a post extending parallel to an axis of rotation of said tool for each said body bore; each said post being sized, aligned and positional to simultaneously enter a respective bore so as to rotate and apply torque to said body when said tool is rotated about the axis thereof,

whereby said tool is operable to at least remove said body from an implant in which said body has been inserted.

Claim 14 In a plug closure for operably closing a top of a channel between two arms of an open headed medical implant, the improvement comprising:

- a) said closure having at least a pair of bores each being positioned in spaced relationship to both an axis of said closure and to a periphery of said closure; said bores being parallel to said axis and being accessible from a top of said closure; and
- b) a break-off head attached to the top of said closure and operably blocking axial access to said bores such that a removal tool cannot be axially inserted into said bores when said break off head is attached to said closure; said break off head being breakable from the closure upon application of a preselected torque to said break-off head, when said closure is positioned between the arms, said break off head being free of openings providing axial access to at least a portion of each of said bores such that said bores are positioned so as to be axially inaccessible by the

removal tool until said break-off head is broken
from said closure.

Claim 15 (Canceled)

IX EVIDENCE APPENDIX

NONE

X RELATED PROCEEDINGS APPENDIX

NONE

Respectfully submitted,

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March 29, 2010

Roger P. Jackson

By

A handwritten signature, appearing to be "R. Jackson", written over a horizontal line.

March 29, 2010

(Date of Signature)